

APPLICANT(S): SIEGEL, Steven

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AMENDMENTS TO THE CLAIMS

Please amend the claims as follows:

1. (Currently amended) A method of treating a [[N]]nervous [[S]]ystem disorder in a subject in need, the method comprising:

- a. [[A]]administering to said subject a first formulation of a drug in complex with a biodegradable polymer, wherein said formulation delivers said drug with pseudo-zero order kinetics *in-vivo*; and
- b. [[A]]administering to said subject a second formulation of said drug in complex with a biodegradable polymer, wherein said formulation delivers said drug substantially faster, *in-vivo*, than said first formulation,

~~Whereby administering said first and second formulation results in therapeutic circulating levels of said drug, for a period of about 14-420 days, whereby said biodegradable polymer comprises a poly(lactide/glycolide) (PLGA) copolymer at a concentration of about 40-90% (w/w) and said drug comprises risperidone, 9-OH-risperidone, or an active metabolite thereof at a concentration of about 10-60% (w/w), thereby being a method of treating said a nervous system disorder.~~

2. (Original) The method of claim 1, wherein said therapeutic circulating levels of said drug range from 0.1 – 10 ng/mL.
3. (Currently amended) The method of claim 2, wherein administering said second formulation results in said circulating levels within a period of about 14-30 days.
4. (Currently amended) The method of claim 2, wherein administering said first formulation results in said circulating levels within a period of about 21-180 days.
5. (Original) The method of claim 2, wherein said circulating levels is sustained for about 14-420 days.

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6. (Original) The method of claim 2, wherein the formulations are in a form of an implant.

7. (Original) The method of claim 6, wherein said implant is inserted subcutaneously.

8. (Original) The method of claim 1, wherein said first formulation comprises complexes of said drug and two or more biodegradable polymers.

9. (Currently amended) The method of claim 8, wherein said complexes vary in terms of drug concentration, polymer composition, or combination thereof.

10. (Original) The method of claim 1, wherein said second formulation comprises complexes of said drug and two or more biodegradable polymers.

11. (Currently amended) The method of claim 10, wherein said complexes vary in terms of drug concentration, polymer composition, or combination thereof.

12. (Original) The method of claim 1, wherein said disorder is AIDS-related dementia, schizophrenia, bipolar disorder, borderline personality disorder (BPD), Alzheimer's disease (AD), psychotic depression or other mental disorders causing confusion, disorganization or psychosis.

13. (Original) The method of claim 6, wherein said implant is disk or rod shaped.

14. (Original) The method of claim 13, wherein said rod shaped implant has a diameter of about 1 to about 2 mm, a length of between about 10 and about 40 mm, or a combination thereof.

15. (Currently amended) The method of claim 1, wherein said drug is at a concentration of about 20-60% (w/w) ~~between about 2 to about 50 percent by weight of said first or second formulation~~.

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16. (Currently amended) The method of claim 2, wherein said drug comprises is-is Risperidone, 9-OH-Risperidone, haloperidol, olanzapine, clozapine, aripiprazole, quetiapine, ziprasidone or a combination thereof.
17. (Original) The method of claim 2, wherein said first formulation and said second formulation are administered within 1-24 hours of each other.
18. (Original) The method of claim 2, wherein said first and second formulations are administered to said subject cyclically.
19. (Original) The method of claim 18, wherein said first and second formulations are administered to said subject when said circulating levels of said drug serum levels are below 1 ng/mL.
20. (Original) The method of claim 18, wherein said first and second formulations are administered to said subject from about 160-200 days, following a first administration of the formulations.
21. (Withdrawn) A kit for sustained delivery of a drug comprising: a first formulation of said drug in complex with a biodegradable polymer, wherein said formulation delivers said drug with pseudo-zero order kinetics in-vivo, and a second formulation of said drug in complex with a biodegradable polymer wherein said second formulation has a rate of release which is faster than said first formulation, in-vivo.
22. (Withdrawn) The kit of claim 21, wherein the combination of said first and second formulation of the kit gives sustained delivery, once administered over a period of about 1 week to about 14 months.
23. (Withdrawn) The kit of claim 21, wherein said biodegradable polymer is copolymer of poly(lactide-glycolide) (PLGA).

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24. (Withdrawn) The kit of claim 23, wherein said PLGA is an atactic or syndiotactic block copolymer of PLA and PGA.
25. (Withdrawn) The kit of claim 23, wherein said PLGA has a molecular weight of from about 10,000 to about 200,000.
26. (Withdrawn) The kit of claim 23, wherein the concentration of d,l-lactide monomer comprising said PLGA ranges from 50% - 100%.
27. (Withdrawn) The kit of claim 21, wherein said biodegradable polymer is polylactide.
28. (Withdrawn) The kit of claim 21, wherein said drug is Risperidone, 9-OH-Risperidone, Haloperidol, Olanzapine, Clozapine, Quetiapine, or a combination thereof.
29. (Withdrawn) The kit of claim 21, wherein the drug content is between 2 and 75% (w/w)
30. (Withdrawn) The kit of claim 21, wherein said first formulation is in the form of an implant.
31. (Withdrawn) The kit of claim 30, wherein said implant is for subcutaneous insertion.
32. (Withdrawn) The kit of claim 30, wherein said implant is rod or disk shaped.
33. (Withdrawn) The kit of claim 32, wherein said rod-shaped disk has a diameter of about 1 to about 2 mm, a length of between about 10 and about 40 mm, or a combination thereof.

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34. (Withdrawn) Use of the kit of claim 21 in treating a psychotic disorders in a subject in need thereof.

35. (Withdrawn) A composition for use in the treatment of psychotic disorders, comprising a poly(lactide/glycolide) (PLGA) copolymer at a concentration of from about 95-98% (w/w), and an antipsychotic agent, at a concentration of from about 2 to about 5% (w/w), wherein the lactide:glycolide ratio of said poly(lactide/glycolide) copolymer is from about 100:0 to 50:50 and wherein said antipsychotic agent is Risperidone or 9-OH-Risperidone.

36. (Withdrawn) The composition of claim 35, wherein said PLGA copolymer concentration is 98% (w/w).

37. (Withdrawn) The composition of claim 35, wherein said PLGA copolymer concentration is 95% (w/w).

38. (Withdrawn) The composition of claim 35, wherein said antipsychotic is 9-OH-Risperidone.

39. (Withdrawn) The composition of claim 38, wherein said PLGA has a molar ratio of lactic monomer to glycolic monomer is 85:15.

40. (Withdrawn) The composition of claim 38, wherein said PLGA has a molar ratio of lactic monomer to glycolic monomer is 75:25.

41. (Withdrawn) The composition of claim 38, wherein said PLGA has a molar ratio of lactic monomer to glycolic monomer is 65:35.

42. (Withdrawn) The composition of claim 38, wherein said PLGA has a molar ratio of lactic monomer to glycolic monomer is 50:50.

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43. (Withdrawn) The composition of claim 38, in the form of a solid implant.

44. (Withdrawn) The composition of claim 43, wherein said implant is in a disk or rod shape.

45. (Withdrawn) The composition of claim 44, wherein said rod shaped implant has a diameter of about 1 to about 4 mm, a length of between about 10 and about 40 mm, or a combination thereof.